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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,293	04/29/2006	Zhiqiang Gao	4276-103	8043

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER	
KAUR, GURPREET	
ART UNIT	**PAPER NUMBER**
1759	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,293	GAO ET AL.	
	Examiner	Art Unit	
	GURPREET KAUR	1759	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/08/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/19/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

1. Claims 1-26 are pending and are being examined.

Response to Amendment

2. Applicant's amendment of 6/08/2010 does not render the application allowable.

Status of the Rejections

3. New grounds of rejection are being made in view of applicant's amendments.

Continued Examination Under 37 CFR 1.114

4. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/28/2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 1, 6-14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patolsky et al. (Redox-Active Nucleic-Acid Replica for the Amplified Bioelectrocatalytic Detection of Viral DNA).

Regarding claims 1 and 18, Patolsky et al. teaches the method of detecting viral DNA with a gold electrode (page 770, col. 1 paragraph 1), the method comprising:

(a) immobilizing capture molecule (thiolated 27-base nucleic acid, 1) which binds with analyte (viral nucleic acid) on the electrode followed by (see Scheme 1 and page 770, col. 1, paragraph 2);

(b) contacting electrode with analyte (viral nucleic acid) of different concentration (see Scheme 1 and page 770, col. 1, paragraph 2). Patolsky does not explicitly teach solution of analyte being in contact with the electrode. However it would be obvious to one of ordinary skill in the art to indicate viral nucleic acid of different concentration is in solution form;

(c) allowing the viral nucleic acid to bind with the capture molecule (thiolated 27-base nucleic acid, 1) to form pair of complexes (double stranded assembly), the complexes form monolayer on the surface of the electrode (see Scheme 1 and page 770, col. 1, paragraph 2), thus it is a first layer on the electrode;

(d) contacting the electrode with electrochemical activator (redox labeled nucleotide, ferrocene dUTP), the ferrocene dUTP is capable of transferring electrons to

allow the detection of analyte upon complex formation (see Scheme 1 and page 770, col. 1, paragraph 2), thus it is inherent the electrochemical activator has net charge complementary to the electrostatic net charge of the complex formed to form a second layer (electrochemical activator layer) on the electrode. Patlosky does not explicitly teaches second layer and first layer together form a conducting bilayer, however, both the second layer and first layer are conducting since the electron transfer occurs between the layers to detect the analyte and then followed by;

(e, f) contacting the electrode with an agent (glucose oxidase) to transfer electron to or from the electrochemical activator or to the electrode to give to an electrical response (see page 770, col.2, ll. 2-3), and followed by;

(g) detecting the viral nucleic acid by comparing the result of electrical current (electrolytic oxidation of glucose) with that of control current (no electrolytic oxidation of glucose (see figure 1B curve b vs curve b in the inset and page 771, col. 1, over to col. 2).

6. Regarding claims 6, 7 and 8, Patolsky teaches the agent (glucose oxidase) is an enzyme capable of transferring electron to and from the electrochemical activator (see page 770, col.2, ll. 2-3).

7. Regarding claims 9-14, Patolsky teaches capture molecule (thiolated 27-base nucleic acid, 1) has complementary sequence to analyte (viral DNA of 7229 bases) to form complex (double stranded assembly), (see Scheme 1 and page 770, col. 1,

paragraph 2) on the electrode. Thus viral DNA has a single stranded region in order to form complex with capture molecule.

8. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patolsky as applied to claims 1 above, and further in view of Zhiqiang et al. (Electrodeposition of Redox Polymer and Co-Electrodeposition of Enzymes by Coordinative Crosslinking, *Angew.Chem.Int. Ed*. 2002, 41, 810-813).

Regarding claims 2-4, Patolsky teaches electrochemical activator is ferrocene dUTP which inherently comprises iron metal ions (see page 770, col. 1, paragraph 2) but Patolsky et al. does not teach electochemical activator is a polymeric redox polymer that comprises metal ions.

However, Zhiqiang et al. teaches a polymeric redox polymer deposit on the electrodes which further conducts electron transfer to oxidized/reduced substrates of the enzyme (see page 810, col. 1 paragraph 1 and col. 2, paragraph 1). The redox polymers are water soluble and readily bound to proteins and enzymes (see page 812 paragraph 1).

Zhiqiang et al. further teaches that polymeric redox polymer comprises osmium metal ions coordinated with the ligands (see scheme 1 on page 811).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to modify the Patolsky activator by linking to polymeric redox polymer as taught by Zhiqiang et al. because polymeric redox polymer is water soluble and readily bound to proteins and enzymes to co-electrodeposit enzymes.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patolsky and Zhiqiang as applied to claim 2 above and further in view of Feldman et al. (U.S. Pat. No. 6,299,757).

Regarding claim 5, Patolsky et al. and Zhiqiang does not teach electrochemical activator comprises poly(vinyl ferrocene) or its derivative.

However, Feldman et al. teaches a redox mediator comprised of poly(vinyl ferrocene) to increase swelling of the redox polymer in water (see col. 21, lines 20-24 and col.22, lines 5-16).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to modify the Patolsky in view of Zhiqinag polymer redox mediator to be comprised of poly(vinyl ferrocene) of Feldman et al. because the use of Feldman et al. activator increase swelling of the redox polymer in water.

10. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patolsky as applied to claims 1 above, and further in view of Willner et al. (U.S. Pat. No. 6,214,205).

Regarding claims 15 and 16, Patolsky does not teach analyte is protein and capture molecule is ligand capable for binding protein.

However, Willner et al. teaches a similar method as that of Patolsky with an electrode disposed with a monolayer comprised of recognition pair comprised of

oligonucleotide-protein, wherein the analyte is the protein and capture molecule is oligonucleotide capable of binding to protein (see col. 3, lines 41-45).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to use Willner recognition pair of oilgonucleotide-protein in the Patolsky method to detect the protein of interest instead of DNA.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patolsky as applied to claims 1 above, and further in view of Umek et al. (U.S. Pub. No. 2003/0124572).

Regarding claim 17, Patolsky does not teach blocking agent immobilized on the electrode.

However, Umek teaches the method of immobilizing the blocking agent to block remaining unoccupied sites on the electrode surface (see paragraph 0076).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to immobilize electrode surface of Patolsky with blocking agent as taught by Umek because blocking agent would block any unoccupied sites on the electrode surface.

12. Claims 19-25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patolsky et al. (Redox-Active Nucleic-Acid Replica for the Amplified Bioelectrocatalytic Detection of Viral DNA) in view of Feldman et al. (U.S. Pat. No. 6,299,757).

Regarding claims 19 and 26, Patolsky et al. teaches an electrode arrangement (see Scheme 1) for detecting viral DNA comprising:

(a) capture molecule (thiolated 27-base nucleic acid, 1) which binds with analyte (viral nucleic acid) on the electrode to form pair of complexes (double stranded assembly), the complexes form monolayer on the surface of the electrode (see Scheme 1 and page 770, col. 1, paragraph 2), thus it is a first layer on the electrode and;

(b) the electrode is then is contacted with electrochemical activator (redox labeled nucleotide, ferrocene dUTP), the ferrocene dUTP is capable of transferring electrons to allow the detection of analyte upon complex formation (see Scheme 1 and page 770, col. 1, paragraph 2), thus it is inherent the electrochemical activator has net charge complementary to the electrostatic net charge of the complex formed to form a second layer (electrochemical activator layer) on the electrode. Patlosky does not explicitly teaches second layer and first layer together form a conducting bilayer, however, both the second layer and first layer are conducting since the electron transfer occurs between the layers to detect the analyte.

Patolsky does not teach electrochemical activator is polymer linked ferrocene.

However, Feldman et al. teaches a redox mediator comprised of poly(vinyl ferrocene) which increase swelling of the redox polymer in water (see col. 21, lines 20-24 and col.22, lines 5-16).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to modify the Patolsky redox mediator to be comprised of poly(vinyl

ferrocene) of Feldman et al. because the use of Feldman et al. activator increase swelling of the redox polymer in water.

13. Regarding claims 20-22, Feldman teaches poly(vinyl ferrocene) as a mediator (see Feldman col. 21, lines 20-24 and col.22, lines 5-16) which inherently contains ferric metal ions and is capable of transferring electrons and Patolsky in view of Feldman does teach mediator is transferring electrons between the analyte and electrode (see Patolsky Scheme 1).

14. Regarding claims 23 and 24, Patolsky teaches contacting the electrode with an agent (glucose oxidase) to transfer electron to or from the electrochemical activator or to the electrode to give to an electrical response (see page 770, col.2, ll. 2-3). Patolsky explicitly teaches that ferrocence units contact or coupled to the glucose oxidase (see page 770, col.2, ll. 2-3 and col. 1, paragraph 1), thus one of ordinary skill in the art can conclude the glucose oxidase is on the ferrocene units or associated with the conducting bilayer.

15. Regarding claim 25, Patolsky teaches the electrode system is used in DNA bioelectronics (see page 770, col. 1, paragraph 1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GURPREET KAUR whose telephone number is

(571)270-7895. The examiner can normally be reached on Monday-Friday 9:00-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ula C. Ruddock can be reached on (571)272-1481. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. K./
Examiner, Art Unit 1759

/Ula C Ruddock/
Supervisory Patent Examiner, Art Unit 1729